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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

UPPJ,R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/736,858

Applicant(s)

HESTER ET AL.

Examiner

Rao M Uppu

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12-14-2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restriction

Restriction to one of the following groups is required under 35 U.S.C. 121:

- I Claims 1-36, drawn to compounds of formula (I) where A is a substituted 1,3-oxazolidin-2-one (ii), their composition and methods of use, classified in class/subclass 514/227.8, 514/376, 544/58.2, and 546/231.
- II Claims 1, 30-37, drawn to compounds of formula (I) where A is a substituted 1, 2-oxazole (i), 1,2-oxazolidin-5-one (iv), or a 5-membered lactones (iii), their composition and methods of use, classified in class/subclass 514/227.8, 514/376, 514/378, 514/432, 514/473, 544/58.2, 548/240, 548/243, and 549/320.

The groups are distinct, each from the other because of the following reasons: Group I embraces plural hetero ring systems in which a substituted 1,3-oxazolidin-2-ones is linked via (un/substituted) phenyl moieties to substructure **B (a)** through **(c)**. Group II embraces substituted 1,2-oxazoles (ii), 1,2-oxazolidin-5-ones (iv), and 5-membered lactones (iii), all of which are linked via (un/substituted) phenyl to substructure **B (a)-(c)**. The two groups refer to structurally dissimilar compounds made independently and used independently. They would be expected to raise different issues of patentability if a compound of Group I was anticipated, the anticipatory reference would not necessarily render obvious the Group II, or vice-versa. They are not art recognized equivalents, as

they are classified diversely from classes/subclasses 514/227.8, 514/376, 514/378, 514/432, 514/473, 544/58.2, 546/231, 548/240 and 549/320, and require separate literature searches.

Applicants are required, in addition to election of a single group, to elect a single disclosed species that belongs to that group, even though this requirement is traversed.

Should applicants traverse on the grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the groups unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other group.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Applicants' attorney Ms. Lucy Yang on September 7, 2001 a provisional election was made with traverse to prosecute Group I and the species recited in Example 13 on page 25 of the Specification. Applicants in replying to this Office action must make affirmation of this election. Claim 37 and the non-elected subject matter in claims 1-36 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected group.

Applicant is reminded that upon the cancellation of claims to a non-elected group, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The elected species N-(((5S)-3-[3-fluoro-4-[1-(methylimino)-1-oxidohexahydro-1- λ 4-thiopyran-4-yl]-2-oxo-1,3-oxazolidin-5-yl)methyl]-propanethioamide, Z-isomer was not found in the search. The search was expanded on the following cores: 1,3-oxazolidin-2-one linked via (un/substituted) phenyl to structure **B (a)-(c)**. Applicants are also advised of MPEP 803.02

Restriction - Markush Claims [R - 2], fourth paragraph, where is stated;

"As an example, in the case of an application with a Markush - type claim drawn to the compound C - R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush - type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush - type claim and claims to the elected species shall be rejected, and claims to the non - elected species would be held withdrawn from further consideration. As in the prevailing practice, **a second action on the rejected claims would be made final.**" (emphasis added).

Claim Rejections – 35 U.S.C. 103 (a)

The following is a quotation of 35 U.S.C. 103 (a) which forms the basis for all obviousness rejections set forth in this office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,688,792. The reference teaches a generic group of 1,3-oxazolidin-2-ones covalently linked via (un/substituted) phenyl to 5- to 7-membered N/S-containing heterocycles that include instant scope of compounds for the same uses. See formula (I) and definition of variables X, R, R¹-R³, and n (columns 1 and 2). The instant claims 1-36 differ from the said reference by reciting a specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425

(CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Claims 1-36 are also rejected under 103 (a) as being unpatentable over US 5,952,324 in view of US 5,688,792. The primary reference (US 5,952,324) teaches a generic group of (un/substituted) phenyloxazolidinones covalently linked to bridged N/S-containing heterocycles that include the instant scope of uses as antibacterial agents. See formula (I) on column 2, and definitions of variables R^1 , R^2 , a-d, and X (columns 2-4). The reference teaches mo- and di-oxygen substitutions on S (i.e., SO and SO₂), but does not teach or fairly suggest (=O) (=N-) substitution taught in the instant application. This deficiency, however, is overcome in the secondary reference (US 5,688,792) which teaches the equivalency of functional groups S, SO, SO₂, and S(=O) (=N-) for structurally similar compounds, all having the said antimicrobial activity (see formula (I) and the definition of variables X, R, R^1 - R^3 , and n, starting from column 1). It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the above teachings to prepare the instantly claimed compounds because they are obvious variants of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such compounds are suggestive of one another and would be expected to share similar antibacterial properties and therefore, the same use as taught for the reference compounds.

Claims 1-36 are also rejected under 103 (a) as being unpatentable over US 5,968,962 in view of US 5,688,792. The primary reference (US 5,968,962) teaches a generic group of (un/substituted) phenyloxazolidinones covalently linked to bridged S-containing heterocycles that include the instant scope of uses as antimicrobial agents. See formula (I) on column 1, and definitions of variables R^1 , R^5 , and X (columns 1 and 2). The reference teaches mo- and di-oxygen substitutions on S (i.e., SO and SO₂), but does not teach or fairly suggest (=O) (=N-) substitution taught in the instant application. This deficiency, however, is overcome in the secondary reference (US 5,688,792) which teaches the equivalency of functional groups S, SO, SO₂, and S(=O) (=N-) for structurally similar compounds, all having the said antibacterial activity (see formula (I) and the definition of variables X, R, R^1 - R^3 , and n, starting from column 1). it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the above teachings to prepare the instantly claimed compounds because they are obvious variants of the reference compounds. One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds because such compounds are suggestive of one another and would be expected to share similar antibacterial properties and therefore, the same use as taught for the reference compounds.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-19, 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i). Claims 8 and 9 are improperly multiply dependent on more than one claim.

Dependency must be in the alternative, i.e., one of claims 2-7.

ii). Claims 18, 19, 22, 24 and 25 are improperly multiply dependent on more than one claim. Dependency must be alternative, i.e., one of claims 14-17.

iii). Claim 20 is dependent on itself. Appropriate correction is requested.

iv). Claim 21 recites R⁵ as C₁₋₄ alkyl substituted with phenyl. There is no antecedent basis for this in claim 20. Note that R⁵ in claim 21 is much broader^a in scope compared to the definition recited in claim 20.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bacterial infections, does not reasonably provide enablement for other microbial infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in

scope with these claims. The instant compounds are described to have potent activities against Gram-positive and Gram-negative bacteria. See page 1, lines 8-10 of the specification. However, the claim 30 recites a method of treatment of microbial infections in general. The microbial infections include a wide range of infections caused by protozoans, fungi, and viruses.

Any inquiry concerning this communication from the examiner should be directed to Rao M. Uppu whose telephone number is (703) 308-3951. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah, can be reached on (703) 308-4716. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Rao M.Uppu, Ph.D.
Examiner
Art Unit 1624



~~Mukund J. Shah~~
Supervisory Examiner
Art Unit 1624

MARK L. GERCH
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